#### **BLANK ROME LLP**

A Pennsylvania LLP

Stephen M. Orlofsky, Esquire David C. Kistler, Esquire Leigh Ann Buziak, Esquire 301 Carnegie Center, 3<sup>rd</sup> Floor Princeton, NJ 08540 Telephone: (609) 750-7700 Facsimile: (609) 750-7701 Orlofsky@blankrome.com Kistler@blankrome.com LBuziak@blankrome.com Attorneys for Defendants

#### MERCHANT & GOULD P.C.

Jeffrey S. Ward (admitted pro hac vice)
Wendy M. Ward (admitted pro hac vice)
Stephen R. Howe (admitted pro hac vice)
Emily M. Wessels (pro hac vice pending)
10 E. Doty Street, Suite 600
Medison, WI, 53703

Madison, WI 53703

Telephone: (608) 280-6751
Facsimile: (612) 332-9081
JWard@MerchantGould.com
WWard@MerchantGould.com
SHowe@MerchantGould.com
EWessels@MerchantGould.com

Attorneys for Defendants

## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

PAR PHARMACEUTICAL, INC., and PAR STERILE PRODUCTS, LLC,

Civil Action No. 3:17-cv-06115-BRM-DEA

Plaintiffs,

Filed Electronically

v.

QUVA PHARMA, INC., STUART HINCHEN, PETER JENKINS, and MIKE RUTKOWSKI,

Defendants.

### **HIGHLY CONFIDENTIAL**

DECLARATION OF STEPHEN R. HOWE IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

- I, Stephen R. Howe, Esq., declare as follows:
- 1. I am an attorney-at-law and associate at the law firm Merchant & Gould, P.C.
  - 2. I am admitted to practice in the states of Illinois and Wisconsin.
- 3. I am making this declaration in support of QuVa's Opposition To Plaintiffs' Motion For Preliminary Injunction.
- 4. Due to the large number of exhibits relating to the present motion and for the ease of the Court, I submit with this declaration a list of exhibits submitted by Defendants with their opposition papers attached hereto as Exhibit A.
- 5. For the ease of the Court and to minimize confusion, Defendants have used sequential numbering and started numbering their exhibits with number 205. Plaintiffs used exhibit numbers 1 through 204 with their moving papers.

6.		
7.		

9.

- 11. Attached hereto as Exhibit 210 is a true and correct copy of US Patent Application Publication 2017/0290881 A1 (Kannan Depo. Ex. 13) as produced as QuVa007902-QuVa008055.
- 12. Attached hereto as Exhibit 211 is a true and correct copy of the CV of John B. White, as produced as QuVa007697-QuVa007701.
- 13. Attached hereto as Exhibit 212 is a true and correct copy of the Declaration of Stuart Hinchen in Support of Defendants' Opposition to Par's Motion for Expedited Discovery dated September 6, 2017, Court docket entry 023-24.

- 14. Attached hereto as Exhibit 213 is a true and correct copy of the Declaration of Harold Patterson in support of Defendants' Opposition to Par's Motion for Expedited Discovery with exhibits dated September 6, 2017, Court dock entry 023-4.
- 15. Attached hereto as Exhibit 214 is a true and correct copy of the Chen email chain with Short et al. dated January 25, 2017, as produced as QuVa002112 QuVa002133.
- 16. Attached hereto as Exhibit 215 is a true and correct copy of the Hinchen email chain with Pera dated February 20, 2017, as produced as QuVa003556 QuVa003357.
- 17. Attached hereto as Exhibit 216 is a true and correct copy of the Jenkins email chain with Cornelius dated April 25, 2017, as produced as OuVa003204 OuVa003205.
- 18. Attached hereto as Exhibit 217 is a true and correct copy of QuVa's supplemental response to Interrogatory 1 (verified) dated October 24, 2017.
- 19. Attached hereto as Exhibit 218 is a true and correct copy of the transcript of deposition of Stuart Hinchen taken November 10, 2017.
- 20. Attached hereto as Exhibit 219 is a true and correct copy of U.S. Patent 9,375,478 to Kenney et al., as produced as QuVa007870-QuVa007901.

21	1.	Attached	hereto	as	Exhibit	220	is	a	true	and	correct	copy	of	the
docume	nt tit	led												
														_
		, a	s produ	ced	by Par a	s Par	-00	)14	1835	– Par	-001486	52.		

- 22. Attached hereto as Exhibit 221 is a true and correct copy of the transcript of deposition of Vinayagam Kannan taken November 7, 2017.
- 23. Attached hereto as Exhibit 222 is a true and correct copy of the transcript of deposition of Jason Crist taken November 3, 2017.
- 24. Attached hereto as Exhibit 223 is a true and correct copy of QuVa Lab Notebook pages (Leeah Depo. Ex. 90) as produced as QuVa005033–QuVa005038.
- 25. Attached hereto as Exhibit 224 is a true and correct copy of the transcript of deposition of Travis Leeah taken November 10, 2017.
- 26. Attached hereto as Exhibit 225 is a true and correct copy of Popenoe et al., "Degradative Studies on Vasopressin and Performic Acid-Oxidized Vasopressin", J. Biol. Chem. 205:133-143 (1953), as produced as QuVa007685-OuVa007696.

27.

- 29. Attached hereto as Exhibit 228 is a true and correct copy of the letter from Travis Leeah to the FDA dated April 19, 2017, as produced as QuVa007770-QuVa007772.
- 30. Attached hereto as Exhibit 229 is a true and correct copy of the resume of Travis Leeah, as produced as QuVa007773- QuVa007775.
- 31. Attached hereto as Exhibit 230 is a true and correct copy of the document titled Exit Interview, (Crist Depo. Ex. 37) dated May 5, 2017, as produced by Par as Par-0002050-Par-0002051.
- 32. Attached hereto as Exhibit 231 is a true and correct copy of the Kennedy email to Ashley Short dated February 2, 2017, as produced by Par as Par-0039147-Par-0039148.
- 33. Attached hereto as Exhibit 232 is a true and correct copy of the Moon email re: Candidate Interview Ashley Short (Senior Analytical Chemist), dated April 7, 2017, as produced as QuVa005135-QuVa005136.

- 34. Attached hereto as Exhibit 233 is a true and correct copy of David Short email chain re: Resume Ashley Short, dated March 26, 2017, as produced as QuVa005144-QuVa005146.
- 35. Attached hereto as Exhibit 234 is a true and correct copy of Ashley Short's resume, as produced as QuVa005230-QuVa005231.
- 36. Attached hereto as Exhibit 235 is a true and correct copy of the document titled "Exit Interview," (Crist Depo. Ex. 36) dated June 27, 2017, as produced by Par as Par-0002048-Par-0002049.
- 37. Attached hereto as Exhibit 236 is a true and correct copy of the Careers@QuVa email to D. Short dated January 7, 2016, as produced as QuVa005182.
- 38. Attached hereto as Exhibit 237 is a true and correct copy of Chinnasamy Subramaniam's resume, as produced as QuVa005315- QuVa005317.
- 39. Attached hereto as Exhibit 238 is a timeline titled "No Contact with Par Employees Was Initiated by QuVa."
- 40. Attached hereto as Exhibit 239 is a true and correct copy of the letter from Carolyn Kaminski to Mr. Subramaniam dated February 25, 2016, as produced as QuVa006254.

- 41. Attached hereto as Exhibit 240 is a true and correct copy of the letter from QuVa to Chinnasamy Subramaniam, dated January 28, 2016, as produced as QuVa006255-QuVa006257.
- 42. Attached hereto as Exhibit 241 is a true and correct copy of the document titled "Exit Interview" (Crist Depo. Ex. 33), dated March 11, 2016, as produced by Par as Par-0002056-Par-0002057.
- 43. Attached hereto as Exhibit 242 is a true and correct copy of David Michael (Mike) Hartley's resume, as produced as QuVa005248-QuVa005251.
- 44. Attached hereto as Exhibit 243 is a true and correct copy of the document titled QuVa Pharma, Inc. Employment Application, dated February 1, 2016, as produced as QuVa005318-QuVa005319.
- 45. Attached hereto as Exhibit 244 is a true and correct copy of the letter from QuVa to David Hartley dated February 3, 2016, as produced as QuVa005660-QuVa005662.
- 46. Attached hereto as Exhibit 245 is a true and correct copy of the document titled "Exit Interview" (Crist Depo. Ex. 31) dated February 12, 2016, as produced by Par as Par-0002052-Par-0002053.
- 47. Attached hereto as Exhibit 246 is a true and correct copy of a letter from Travis McGrady to Rick Zuehlk, dated February 1, 2016, as produced by Par as Par-0002810.

- 48. Attached hereto as Exhibit 247 is a true and correct copy of a document titled "2015 Mid Year Performance Appraisal," listing Travis McGrady, as produced by Par as Par-0003438-Par-0003440.
- 49. Attached hereto as Exhibit 248 is a true and correct copy of the resume of Travis McGrady, as produced as QuVa005240-QuVa005242.
- 50. Attached hereto as Exhibit 249 is a true and correct copy of the document titled QuVa Pharma, Inc. Employment Application, dated January 20, 2016, as produced as QuVa005320-QuVa005321.
- 51. Attached hereto as Exhibit 250 is a true and correct copy of the McGrady email to Rhoades dated December 17, 2015, as produced as QuVa006390.
- 52. Attached hereto as Exhibit 251 is a true and correct copy of the letter from QuVa to Travis McGrady, dated January 22, 2016, as produced as QuVa007644-QuVa007646.
- 53. Attached hereto as Exhibit 252 is a true and correct copy of the document titled "Qualitest Pharmaceuticals Exit Interview Questionnaire" as produced by Par as Par-0038850-Par-0038853.
- 54. Attached hereto as Exhibit 253 is a true and correct copy of the Fillarini email to Soliman dated April 4, 2017, as produced as QuVa005775.

- 55. Attached hereto as Exhibit 254 is a true and correct copy of the letter from QuVa to Ahmed Soliman, dated April 21, 2016, as produced as QuVa005900-QuVa005902.
- 56. Attached hereto as Exhibit 255 is a true and correct copy of the resume of Ahmed Soliman resume, as produced as QuVa006753-QuVa006755.
- 57. Attached hereto as Exhibit 256 is a true and correct copy of the document titled "Exit Interview" (Crist Depo Ex. 35) dated October 14, 2016, as produced by Par as Par-0002054-Par-0002055.
- 58. Attached hereto as Exhibit 257 is a true and correct copy of the resume of Guy Thompson, as produced as QuVa005244.
- 59. Attached hereto as Exhibit 258 is a true and correct copy of the email chain between Careers@QuVa and David Short dated January 21, 2016, as produced as QuVa006029.
- 60. Attached hereto as Exhibit 259 is a true and correct copy of the November 1, 2016 letter from Guy Thompson to QuVa, as produced as OuVa007588-OuVa007592.
- 61. Attached hereto as Exhibit 260 is a true and correct copy of the QuVa employment offer to Guy Thompson, as produced as QuVa007595-QuVa007597.
- 62. Attached hereto as Exhibit 261 is a true and correct copy of the resume of Donna Kohut, as produced as QuVa007679-QuVa007682.

- 63. Attached hereto as Exhibit 262 is a true and correct copy of the letter from QuVa to Donna Kohut, dated August 28, 2015, as produced as QuVa007579-QuVa007581.
- 64. Attached hereto as Exhibit 263 is a true and correct copy of resume of Mike Rutkowski, as produced as QuVa006386-QuVa006490.
- 65. Attached hereto as Exhibit 264 is a true and correct copy of the document titled "A history of the OOS problem", BioPharm International, as produced as RutkowskiHardDrive-1-0000001-003.
- 66. Attached hereto as Exhibit 265 is a true and correct copy of the document titled "Position Paper: Segregation of Production Activities for Human and Animal Health Products", as produced as Rutkowski HardDrive-1-0000004-008.
- 67. Attached hereto as Exhibit 266 is a true and correct copy of the Braun internal memorandum from Gall re B. the solution, dated January 16, 2014, as produced as Rutkowski HardDrive-1-0000009-012.
- 68. Attached hereto as Exhibit 267 is a true and correct copy of the April 3, 2017 letter from Mike Rutkowski, as produced as Rutkowski HardDrive-1-0000013.

- 69. Attached hereto as Exhibit 268 is a true and correct copy of a letter from Mike Rutkowski to Rochester employees, as produced as RutkowskiHardDrive-1-0000014.
- 70. Attached hereto as Exhibit 269 is a true and correct copy the document titled \_\_\_\_\_\_, as produced as Rutkowski HardDrive-1-0000015-018.
- 71. Attached hereto as Exhibit 270 is a true and correct copy of the document titled , as produced as Rutkowski HardDrive-1-0000019-021.
- 72. Attached hereto as Exhibit 271 is a true and correct copy of a document titled as produced as Rutkowski HardDrive-1-0000022-023.
- 73. Attached hereto as Exhibit 272 is a true and correct copy of the document titled \_\_\_\_\_\_\_\_, as produced as Rutkowski HardDrive-1-000024.
- 74. Attached hereto as Exhibit 273 is a true and correct copy of a letter from Mike Rutkowski letter, as produced as Rutkowski HardDrive-1-0000025.
- 75. Attached hereto as Exhibit 274 is a true and correct copy of a document with file name ISO 8 clean room areas cleaning sanitization, as produced as Rutkowski HardDrive-1-0000026-037.

- 76. Attached hereto as Exhibit 275 is a true and correct copy of a document titled \_\_\_\_\_\_\_, as produced as Rutkowski HardDrive-1-0000038-043.
- 77. Attached hereto as Exhibit 276 is a true and correct copy of a document titled , as produced as Rutkowski HardDrive-1-0000044-045.
- 78. Attached hereto as Exhibit 277 is a true and correct copy of a letter from Mike Rutkowski, as produced as Rutkowski HardDrive-1-0000046.
- 79. Attached hereto as Exhibit 278 is a true and correct copy of a letter from Mike Rutkowski to The Rock dated March 30, 2017, as produced as Rutkowski HardDrive-1-0000047.
- 80. Attached hereto as Exhibit 279 is a true and correct copy of a letter from Mike Rutkowski to Terry Coughlin, dated March 28, 2017, as produced as Rutkowski HardDrive-1-0000048.
- 81. Attached hereto as Exhibit 280 is a true and correct copy of a document titled , as produced as Rutkowski HardDrive-1-0000049-051.
- 82. Attached hereto as Exhibit 281 is a true and correct copy of a document titled , as produced as Rutkowski HardDrive-1-0000052-054.

- 83. Attached hereto as Exhibit 282 is a true and correct copy of a document titled , as produced as Rutkowski HardDrive-1-0000055.
- 84. Attached hereto as Exhibit 283 is a true and correct copy of a letter from Mike Rutkowski to Marian Gustafson, as produced as Rutkowski HardDrive-1-0000056.
- 85. Attached hereto as Exhibit 284 is a true and correct copy of a document titled , as produced as Rutkowski HardDrive-1-0000057-058.
- 86. Attached hereto as Exhibit 285 is a true and correct copy of a document titled WG Henschen Job Description: Operations Manager, as produced as Rutkowski HardDrive-1-0000059-060.
- 87. Attached hereto as Exhibit 286 is a true and correct copy of a document titled \_\_\_\_\_\_\_\_, as produced as Rutkowski HardDrive-1-0000061-064.
- 88. Attached hereto as Exhibit 287 is a true and correct copy of a document titled

  as produced as Rutkowski HardDrive-1-0000065-068.

89. Attached hereto as Exhibit 288 is a true and correct copy of	of a
document titled	
, as produced as Rutkowski HardDrive-1-0000069-072.	
90. Attached hereto as Exhibit 289 is a true and correct copy of	of a
document titled , as produced	d as
Rutkowski HardDrive-1-0000073-075.	
91. Attached hereto as Exhibit 290 is a true and correct copy of	of a
document titled	,
as produced as Rutkowski HardDrive-1-0000076-078.	
92. Attached hereto as Exhibit 291 is a true and correct copy of an e	xcel
92. Attached hereto as Exhibit 291 is a true and correct copy of an estimate the sheet with the file name and correct copy of an estimate the sheet with the file name.	
sheet with the file name , as produced as Rutkov	wski
sheet with the file name , as produced as Rutkov HardDrive-1-0000079.	wski of a
sheet with the file name, as produced as Rutkov HardDrive-1-0000079.  93. Attached hereto as Exhibit 292 is a true and correct copy of	wski of a
sheet with the file name, as produced as Rutkov HardDrive-1-0000079.  93. Attached hereto as Exhibit 292 is a true and correct copy of document titled, as produced as Rutkowski HardDrive.	wski of a e-1-
sheet with the file name , as produced as Rutkov HardDrive-1-0000079.  93. Attached hereto as Exhibit 292 is a true and correct copy of document titled , as produced as Rutkowski HardDrive 0000080.	wski of a e-1-

- 95. Attached hereto as Exhibit 294 is a true and correct copy of a PowerPoint presentation titled \_\_\_\_\_\_\_, as produced as RutkowskiHardDrive-1-0000084-089.
- 96. Attached hereto as Exhibit 295 is a true and correct copy of a document titled , as produced as Rutkowski HardDrive-1-0000090-093.
- 97. Attached hereto as Exhibit 296 is a true and correct copy of a photograph of the cover of the COW book. The entire book is provided as QuVa004484-4944.
- 98. Attached hereto as Exhibit 297 is a true and correct copy of FDA's Quality Metrics Report Program: Submission of Quality Metrics Data, as produced as QuVa007683-QuVa007684.
- 99. Attached hereto as Exhibit 298 is a true and correct copy of the transcript of Rutkowski deposition taken October 27, 2017.
- 100. Attached hereto as Exhibit 299 is a true and correct copy of the Hinchen email chain with Rhoades dated August 17, 2015, as produced as QuVa006479-QuVa006480.
- 101. Attached hereto as Exhibit 300 is a true and correct copy of the David Short email chain with Hinchen dated September 4, 2015, as produced as QuVa006636-QuVa006637.

- 102. Attached hereto as Exhibit 301 is a true and correct copy of the Kohut email chain with Kaminsky dated January 11, 2016, as produced as QuVa006688.
- 103. Attached hereto as Exhibit 302 is a true and correct copy of the Chinnasamy email to Careers at QuVa dated January 06, 2016, as produced as QuVa006689.
- 104. Attached hereto as Exhibit 303 is a true and correct copy of the Kaminsky email chain with David Short dated March 9, 2016, as produced as QuVa006751-QuVa006752.
- 105. Attached hereto as Exhibit 304 is a true and correct copy of David Short's Resume, as produced as QuVa007675-QuVa007678.
- 106. Attached hereto as Exhibit 305 is a true and correct copy of Stephen J. Rhoades' Resume, as produced as QuVa007776-QuVa007778.
- 107. Attached hereto as Exhibit 306 is a true and correct copy of Technical Report No. 13 (Revised) Fundamentals of an Environmental Monitoring Program, PDA 2014, as produced as QuVa007831-QuVa007869.
- 108. Attached hereto as Exhibit 307 is a true and correct copy of Technical Report No. 22 (Revised 2011) Process Simulation for Aseptically Filled Products, PDA 2011, as produced as QuVa007781-QuVa007830.

- 109. Attached hereto as Exhibit 308 is a true and correct copy of a document titled Proprietary Information and Nondisclosure Agreement, as produced as QuVa007779-QuVa007780.
- 110. Attached hereto as Exhibit 309 is a true and correct copy of USP 1790, Visual Inspection of Injections, First Supplement to USP 40-NF 35, pp. 8099-8119 dated December 1, 2017, as produced as QuVa008214- QuVa008234.
- 111. Attached hereto as Exhibit 310 is a true and correct copy of Technical Report No. 36, Current Practices in the Validation of Aseptic Processing 2001, PDA Journal of Pharmaceutical Science and Technology, Vol. 56, May-June 2002, dated May 1, 2002, as produced as QuVa008176-QuVa008213.
- 112. Attached hereto as Exhibit 311 is a true and correct copy of Technical Report No. 20, Report on Survey of Current Industry Gowning Practices, PDA Journal of Pharmaceutical Science and Technology, Sup. Vol. 44, No. S2 (1990) dated January 1, 1990, as produced as QuVa008170-QuVa008175.
- 113. Attached hereto as Exhibit 312 is a true and correct copy of ISO 13408-1 2008E, Aseptic Processing of Health Care Products, Part 1: General Requirements dated June 15, 2008, as produced as QuVa008068-QuVa008121.
- 114. Attached hereto as Exhibit 313 is a true and correct copy of USP 38
  (797) Pharmaceutical Compounding Sterile Preparations dated December 1,
  2015, as produced as QuVa008235-QuVa008279

- 115. Attached hereto as Exhibit 314 is a true and correct copy of Schwartz, "UPLC<sup>TM</sup>: An Introduction and Review", Journal of Liquid Chromatography and Related Technologies, 28:1252-1263 (2005), as produced as QuVa008159-QuVa008169.
- 116. Attached hereto as Exhibit 315 is a chart comparing QuVa 503B compounding with Par traditional sterile manufacturing.
- 117. Attached hereto as Exhibit 316 is a true and correct copy of Nema et al., "Excipients and Their Use in Injectable Products", PDA J. Pharm. Sci. and Tech., 51:166-171 (1997), as produced as QuVa008128-QuVa008135.
- 118. Attached hereto as Exhibit 317 is a true and correct copy of the CV of Rodolfo Pinal, as produced as QuVa008136-QuVa008158.
- 119. Attached hereto as Exhibit 318 is a true and correct copy of the list of materials considered by Rodolfo Pinal.

120.		
	I	
121.		

- 122. Attached hereto as Exhibit 321 is a true and correct copy of Hyodo, Chapter 6A, Vasopressin (2016), as produced as QuVa008482-QuVa008486.
- 123. Attached hereto as Exhibit 322 is a true and correct copy of Streitwieser, Heathcock, "Introduction to Organic Chemistry" 2nd Ed., p. 54.
- 124. Attached hereto as Exhibit 323 is a true and correct copy of the transcript of Peter Jenkins deposition as an individual taken November 9, 2017.
- 125. Attached hereto as Exhibit 324 is a true and correct copy of the transcript of Peter Jenkins deposition as 30(b)(6) witness taken November 9, 2017.
- 126. Attached hereto as Exhibit 325 is a true and correct copy of Par's Supplemental Responses to Defendants' First Set of Interrogatories Nos. 10-12 (Crest Depo. Ex. 3) dated October 26, 2017.
- 127. Attached hereto as Exhibit 326 is a true and correct copy of the document titled "Exit Interview" (Crist Depo. Ex. 27) dated October 23, 2015, as produced by Par as Par-0002058-Par-0002059.
- 128. Attached hereto as Exhibit 327 is a true and correct copy of the document titled "Exit Interview" (Crist Depo. Ex. 29), as produced by Par as Par-0002060-Par-0002061.
- 129. Attached hereto as Exhibit 328 is a true and correct copy of Rutkowski email chain with Campanelli (Crist Depo Ex. 39) dated April 10, 2017, as produced by Par as Par-0038733-Par-0038735.

- 130. Attached hereto as Exhibit 329 is a true and correct copy of the document titled "Mutual Agreement to Arbitrate Claims" dated February 11, 2016, as produced by Par as Par-0001547-Par-0001549.
- 131. Attached hereto as Exhibit 330 is a true and correct copy of the Kaminsky email chain with Hinchen dated October 12, 2015, as produced as QuVa006510-QuVa006512.
- 132. Attached hereto as Exhibit 331 is a true and correct copy of the document titled "Recommendation on the Validation of Aseptic Processes" PL 007-6, dated January 1, 2011, as produced as QuVa008487-QuVa008506.
- 133. Attached hereto as Exhibit 332 is a true and correct copy of White, "Aseptic Process Simulation", J. Validation Tech (Winter 2010) pp 39-42 dated December 1, 2010, as produced as QuVa008507-QuVa008510.
- 134. Attached hereto as Exhibit 333 is a true and correct copy of "Media fill simulations", Focus on Pharma, Manufacturing Chemist, Quality Assurance dated November 2014, as produced as QuVa008479-QuVa008481.
- 135. Attached hereto as Exhibit 334 is a true and correct copy of the resume of Ludmila Yaheva, as produced as QuVa008511-QuVa008513.
- 136. Attached hereto as Exhibit 335 is a true and correct copy of the resume of Chen Jianping, as produced as QuVa008514-QuVa008517.

- 137. Attached hereto as Exhibit 336 is a true and correct copy of the website page titled "Par People Achieving Results," found at https://www.parpharm.com/generics.php, accessed on December 1, 2017.
- 138. Attached hereto as Exhibit 337 is a true and correct copy of the document titled "Form S-1 Registration Statement Under the Securities Act of 1933: Par Pharmaceutical Holdings, Inc.", dated March 12, 2015.
- 139. Attached hereto as Exhibit 338 is a true and correct copy of the document titled "Endo Completes Acquisition of Par Pharmaceutical and Provides Financial Guidance", Endo International plc Press Release dated September 28, 2015.
- 140. Attached hereto as Exhibit 339 is a true and correct copy of the website page titled "Overview," found at http://www.endo.com/our-companies/overview, accessed on November 30, 2017.
- 141. Attached hereto as Exhibit 340 is a true and correct copy of the website page titled "Careers," found at http://www.quvapharma.com/careers/, accessed on November 30, 2017.
- 142. Attached hereto as Exhibit 341 is a true and correct copy of the document titled "Center for Drug Evaluation and Research Application Number 204485Orig1s000 Medical Review(s)," dated April 4, 2014.

- 143. Attached hereto as Exhibit 342 is a true and correct copy of Vasostrict Label, Par Pharmaceutical Companies, Inc., April 17, 2014, as accessed via www.accessdata.fda.gov.
- 144. Attached hereto as Exhibit 343 is a true and correct copy of the document titled "Some Selected History of Oxytocin and Vasopressin," The National Institute of Mental Health, accessed through www.nimh.nih.gov on November 30, 2017.
- 145. Attached hereto as Exhibit 344 is a true and correct copy of the website page "Warner-Lambert & King In \$125M Deal," The Pharma Letter, April 3, 1998, found at https://www.thepharmaletter.com/article/warner-lambert-king-in-125m-deal, accessed on November 30, 2017.
- 146. Attached hereto as Exhibit 345 is a true and correct copy of the document titled "Form 8-K: King Pharmaceuticals, Inc.," dated July 19, 2007.
- 147. Attached hereto as Exhibit 346 is a true and correct copy of the document titled "Vasopressin Injection Drug Shortage Notice," found at https://www.drugs.com/drug-shortages/vasopressin-injection-795, as accessed on November 30, 2017.
- 148. Attached hereto as Exhibit 347 is a true and correct copy of the document titled "Declaration of Peter Jenkins in Support of Defendants' Opposition to Par's Motion for Expedited Discovery," dated September 5, 2017.

- 149. Attached hereto as Exhibit 348 is a true and correct copy of the website page titled "What are unapproved drugs and why are they on the market?" found at https://www.fda.gov/AboutFDA/Transparency/Basics/ucm213030.htm, as accessed on November 30, 2017.
- 150. Attached hereto as Exhibit 349 is a true and correct copy of Defendants' Opposition to Par's Motion for Expedited Discovery, dated September 7, 2017.
- 151. Attached hereto as Exhibit 350 is a true and correct copy of the document titled "Guidance for FDA Staff and Industry: Marketed Unapproved Drugs Compliance Policy Guide," Center for Drug Evaluation and Research at the FDA, dated September 19, 2011.
- 152. Attached hereto as Exhibit 351 is a true and correct copy of "Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act," Food and Drug Administration, Updated July 1, 2017.
- 153. Attached hereto as Exhibit 352 is a true and correct copy of the website page titled "Compounding and the FDA: Questions and Answers," found at https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm, as accessed on November 30, 2017.

- 154. Attached hereto as Exhibit 353 is a true and correct copy of the Vasostrict Label, Par Pharmaceutical Companies, Inc., December 21, 2016, as accessed via www.accessdata.fda.gov.
- 155. Attached hereto as Exhibit 354 is a true and correct copy of Roman L. Weil, Daniel G. Lentz, and Elizabeth A. Evans, eds., Litigation Services Handbook: The Role of the Financial Expert, Sixth edition, John Wiley and Sons, 2017, Chapter 4: "Damages Theories and Causation Issues" (2017).
- 156. Attached hereto as Exhibit 355 is a true and correct copy of an image of the Par Pharmaceutical website page "Par Product Summary: Vasostrict," as accessed via www.parsterileproducts.com/products/products/vasostrict/.
- 157. Attached hereto as Exhibit 356 is a true and correct copy of a document titled "Update: FDA revises final guidances on interim policy for certain bulk drug substances used in compounding," as accessed via www.fda.gov/drugs/drugsafety/ucm502075.htm on December 6, 2017.
- 158. Attached hereto as Exhibit 357 is a true and correct copy of the document titled ""ENDO International PLC: 4Q Wrap-Up: Modest Sales Beat, but Lowering Ests on Pessimistic '17 Guide," Leerink, February 28, 2017, as produced as Par-0040106-Par-0040116
- 159. Attached hereto as Exhibit 358 is a true and correct copy of the document titled Truven Health Analytics, "AWP Policy," revised October 1, 2014.

- 160. Attached hereto as Exhibit 359 is a true and correct copy of the document titled "RED BOOK," as accessed via www.truvenhealth.com.
- 161. Attached hereto as Exhibit 360 is a true and correct copy of Michael Hiltzik, "The little-known FDA program that's driving drug prices higher," LA Times, September 23, 2015.
- 162. Attached hereto as Exhibit 361 is a true and correct copy of "Some Drug Price Hikes Due to FDA Safety Program," News Max, October 7, 2015.
- 163. Attached hereto as Exhibit 362 is a true and correct copy of the document titled dated November 8, 2017, as produced by Par as Par-0039612-Par-0039614.
- 164. Attached hereto as Exhibit 363 is a true and correct copy of the document titled as produced by Par as Par-0040199.
- 165. Attached hereto as Exhibit 364 is a true and correct copy of the document titled "ENDO International PLC: Lowering Ests, Persistent US Gx Headwinds, Lowering PT to \$12," Leerink Partners dated January 24, 2017, as produced by Par as Par-0040117-Par-0040127.
- 166. Attached hereto as Exhibit 365 is a true and correct copy of the document titled "Form 10-K: Endo International Plc" for fiscal year ended December 31, 2015.

- 167. Attached hereto as Exhibit 366 is a true and correct copy of the document titled "Form 10-K: Endo International Plc" for fiscal year ended December 31, 2016.
- 168. Attached hereto as Exhibit 367 is a true and correct copy of the document titled "Form 10-Q: Endo International Plc" for quarterly period ended September 30, 2017.
- 169. Attached hereto as Exhibit 368 is a true and correct copy of the document titled "Par Sterile Products Products Database," as produced by Par as Par-0040158-Par-0040161.
- 170. Attached hereto as Exhibit 369 is a true and correct copy of the Par Pharmaceutical Product Catalog, as accessed at www.parpharm.com/product-catalog.php on December 5, 2017.
- 171. Attached hereto as Exhibit 370 is a true and correct copy of the document titled "Center for Drug Evaluation and Research Application Number 204485Orig1s000 Summary Review," dated March 20, 2014.
- 172. Attached hereto as Exhibit 371 is a true and correct copy of the FDA.gov website page for "Outsourcing Facilities," as accessed at https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Pharmacy Compounding/ucm393571.htm on November 30, 2017.

- 173. Attached hereto as Exhibit 372 is a true and correct copy of Jennifer Gudeman, Michael Jozwiakowski, John Chollet, and Michael Randell, "Potential risks of pharmacy compounding," Drug RD, Vol 13, March 23, 2013
- 174. Attached hereto as Exhibit 373 is a true and correct copy of "American Regent, Inc. Initiates Voluntary Recall of Seventeen Lots of Vasopressin Injection, USP, Multiple Dose Vials due to Sub-Potency," PR Newswire, August 3, 2011.
- 175. Attached hereto as Exhibit 374 is a true and correct copy of a document titled "PHAST Prescription," Symphony Health.
- 176. Attached hereto as Exhibit 375 is a true and correct copy of Hoefle, "The Early History of Parke-Davis and Company", Bulletin for the History of Chemistry 25, No. 1 (2000).
- 177. Attached hereto as Exhibit 376 is a true and correct copy of the letter from the FDA to Mr. Vasquez re: NDA Approval, dated April 17, 2014.
- 178. Attached hereto as Exhibit 377 is a true and correct copy of the document titled as produced by Par as Par-0039661- Par-0039662.
- 179. Attached hereto as Exhibit 378 is a true and correct copy of the website www.americanregent.com/Our\_Company.aspx as accessed on December 4, 2017.

- 180. Attached hereto as Exhibit 379 is a true and correct copy of the document titled Center for Drug Evaluation and Research Approval Package for Application Number: 204485Orig1s004, dated December 16, 2016.
- 181. Attached hereto as Exhibit 380 is a true and correct copy of the document titled "How did the Federal Food, Drug, and Cosmetic Act come about?" from www.fda.gov.
- 182. Attached hereto as Exhibit 381 is a true and correct copy of the document titled Symphony Health Integrated Pharmaceutical Audit Suite data.
- 183. Attached hereto as Exhibit 382 is a true and correct copy of the Truven Health Analytics website Red Book Online Product Details pages for Pitressin and Vasostrict, as accessed on December 1, 2017.
- 184. Attached hereto as Exhibit 383 is a true and correct copy of the list of materials considered by Patterson.
- 185. Attached hereto as Exhibit 384 is a true and correct copy of the CV of Brian T. Wolfinger.
- 186. Attached hereto as Exhibit 385 is a true and correct copy of the list of materials considered by Brian T. Wolfinger.
- 187. Attached hereto as Exhibit 386 is a true and correct copy of a chart titled "Thumb Drive Identification Chart."

- 188. Attached hereto as Exhibit 387 is a true and correct copy of a series of photographs of the Lenovo drive inspected by Brian T. Wolfinger.
- 189. Attached hereto as Exhibit 388 is a true and correct copy of the image log for the image provided of Ashley Short's hard drive.
- 190. Attached hereto as Exhibit 389 is a true and correct copy of the image log for the image provided of Chinnasamay Subramaniam's hard drive.
- 191. Attached hereto as Exhibit 390 is a true and correct copy of the image log for the image provided of Mike Rutkowski's hard drive.
- 192. Attached hereto as Exhibit 391 is a true and correct copy of a screenshot provided from the forensic analysis conducted by Brian T. Wolfinger.
- 193. Attached hereto as Exhibit 392 is a true and correct copy a screenshot provided from the forensic analysis conducted by Brian T. Wolfinger, containing the title "Post Departure Disk Defragmentation: Screenshot of Software Analysis."
- 194. Attached hereto as Exhibit 393 is a true and correct copy of a PDF printout of the Lenovo Website as accessed on December 5, 017 at: https://pcsupport.lenovo.com/...r900vwzf?linkTrack=Homepage%3ABody\_Search+Products&searchType=6&keyWordSearch=R900VWZF
- 195. Attached hereto as Exhibit 394 is a true and correct copy of a PDF printout of the LaptopMag Website as accessed on December 1, 017 at: https://www.laptopmag.com/articles/defragment-hard-drive-windows

- 196. Attached hereto as Exhibit 395 is a true and correct copy of a document titled "Defrag & Summary Data" prepared by Wolfinger Forensics.
- 197. Attached hereto as Exhibit 396 is a true and correct copy of a screenshot provided from the forensic analysis conducted by Brian T. Wolfinger, containing the heading: Operating System Install Dates for Rutkowski and Subramaniam.
- 198. Attached hereto as Exhibit 397 is a true and correct copy of the set documents containing bates numbers Par-0040242 to Par-0040253 as produced by Par in this litigation.
- 199. Attached hereto as Exhibit 398 is a true and correct copy of a screenshot provided from the forensic analysis conducted by Brian T. Wolfinger.
- 200. Attached hereto as Exhibit 399 is a true and correct copy of the set of documents containing bates numbers OMM-SC-0000047 OMM-SC-0000053 as produced by Par in this litigation.
- 201. Attached hereto as Exhibit 400 is a true and correct copy of the document containing bates number OMM-SC-0000001 as produced by Par in this litigation.
- 202. Attached hereto as Exhibit 401 is a true and correct copy of Par Supplemental Responses to Interrogatories Nos. 1, 5, 8 and 9 dated October 30, 2017.

- 203. Attached hereto as Exhibit 402 is a true and correct copy of Bi et al., "HPLC Method for Quantification of Arginine Containing Vasopressin", J. Liq. Chrom. & Rel. Technol. 22(4):551-560 (1999).
- 204. Attached hereto as Exhibit 403 is a true and correct copy of Hermann et al., "Urinary excretion of angiotensin I, II, arginine vasopressin and oxytocin in patients with anphylactoid reactions", Clinical and Experimental Allergy, 22:845-853 (1992).
- 205. Attached hereto as Exhibit 404 is a true and correct copy of Tsukakzaki et al, "Development of a High-Sensitivity Quantitation Method for Arginine Vasopressin by High-Performance Liquid Chromatography Tandem Mass Spectrometry, and Comparison with Quantitative Values by Radioimmunoassay", Analytical Sciences, 32:153-159 (February 2016).
- 206. Attached hereto as Exhibit 405 is a true and correct copy of Zhang et al. "Development and validation of a highly sensitive LC-MS/MS assay for the quantification of arginine vasopressin in human plasma and urine: Application in preterm neonates and child", J. Pharm. & Biomedical Analysis, 99:67-73 (2014).
- 207. Attached hereto as Exhibit 406 is a true and correct copy of the CV of Mohan Rao.
- 208. Attached hereto as Exhibit 407 is a true and correct copy of the list of materials considered by Mohan Rao.

- 209. Attached hereto as Exhibit 408 is a true and correct copy of the document titled Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act, Guidance for Industry, January 2017.
- 210. Attached hereto as Exhibit 409 is a true and correct copy of the transcript of September 29, 2017 hearing on expedited discovery in the instant action.
- 211. Attached hereto as Exhibit 410 is a true and correct copy of the Declaration of Ahmed Soliman filed concurrently herewith.
- 212. Attached hereto as Exhibit 411 is a true and correct copy of the Declaration of Angela Palomarez filed concurrently herewith.
- 213. Attached hereto as Exhibit 412 is a true and correct copy of the Declaration of Ashley Short filed concurrently herewith.
- 214. Attached hereto as Exhibit 413 is a true and correct copy of the Declaration of Chinnasamy Subramaniam filed concurrently herewith.
- 215. Attached hereto as Exhibit 414 is a true and correct copy of the Declaration of David Michael Hartley filed concurrently herewith.
- 216. Attached hereto as Exhibit 415 is a true and correct copy of the Declaration of David Short filed concurrently herewith.

- 217. Attached hereto as Exhibit 416 is a true and correct copy of the Declaration of Donna Kohut filed concurrently herewith.
- 218. Attached hereto as Exhibit 417 is a true and correct copy of the Declaration of Guy Thompson filed concurrently herewith.
- 219. Attached hereto as Exhibit 418 is a true and correct copy of the Declaration of John B. White filed concurrently herewith.
- 220. Attached hereto as Exhibit 419 is a true and correct copy of the Declaration of Mike Rutkowski filed concurrently herewith.
- 221. Attached hereto as Exhibit 420 is a true and correct copy of the Declaration of Stephen Rhoades filed concurrently herewith.
- 222. Attached hereto as Exhibit 421 is a true and correct copy of the Declaration of Stuart Hinchen filed concurrently herewith.
- 223. Attached hereto as Exhibit 422 is a true and correct copy of the Declaration of Travis Leeah filed concurrently herewith.
- 224. Attached hereto as Exhibit 423 is a true and correct copy of the Declaration of Travis McGrady filed concurrently herewith.
- 225. Attached hereto as Exhibit 424 is a true and correct copy of the Declaration of Harold Patterson filed concurrently herewith.
- 226. Attached hereto as Exhibit 425 is a true and correct copy of the Declaration of Dr. Rodolfo Pinal filed concurrently herewith.

- 227. Attached hereto as Exhibit 426 is a true and correct copy of the Declaration of Brian T. Wolfinger filed concurrently herewith.
- 228. Attached hereto as Exhibit 427 is a true and correct copy of the Declaration of Dr. Mohan P. Rao filed concurrently herewith.

I declare under penalty of perjury that the foregoing is true and correct. Executed on December 8, 2017.

Stephen R. Howe, Esq.

## **EXHIBIT A**

# LIST OF DEFENDANTS' EXHIBITS SUBMITTED WITH OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

### **EXHIBIT NOS. 205 – 427**

EX NO.	DESCRIPTION	DATE	BATES
205		03-31-2016	QuVa007662- QuVa007674
206		08-01-2017	QuVa007650- QuVa007661
207		05-02-2014	QuVa007763- QuVa007769
208		12-02-2015	QuVa007702- QuVa007754
209		11-28-2017	QuVa007755- QuVa007762
210	US Patent Application Publication 2017/0290881 A1 (Kannan Depo. Ex. 13)	10-12-2017	QuVa007902- QuVa008055
211	CV of John B. White		QuVa007697- QuVa007701
212	Declaration of Stuart Hinchen in Support of Defendants' Opposition to Par's Motion for Expedited Discovery, DI 023-4.	09-06-2017	
213	Declaration of Harold Patterson in support of Defendants' Opposition to Par's Motion for Expedited Discovery with exhibits, DID 023-4.	09-06-2017	
214	Chen email chain with Short et al	01-25-2017	QuVa002112 - QuVa002133
215	Hinchen email chain with Pera	02-20-2017	QuVa003556 – QuVa003357
216	Jenkins email chain with Cornelius	04-25-2017	QuVa003204- QuVa003205
217	QuVa Supplemental Response to Interrogatory 1 (verified)	10-24-2017	

218	Transcript of deposition of Stuart Hinchen	11-10-2017	
219	U. S. Patent 9,375,478 Kenney et al.	06-28-2016	QuVa007870- QuVa007901
220		11-24-2015	Par-0014835-Par-0014862
221	Transcript of deposition of Vinayagam Kannan	11-07-2017	
222	Transcript of deposition of Jason Crist	11-03-2017	
223	QuVa Lab Notebook pages (Leeah Depo. Ex. 90)	10-17-2017	QuVa005033- QuVa005038
224	Transcript of deposition of Travis Leeah	11-10-2017	
225	Popenoe et al., "Degradative Studies on Vasopressin and Performic Acid-Oxidized Vasopressin", J. Biol. Chem. 205:133-143 (1953)	06-15-1953	QuVa007685- QuVa007696
226			QuVa008062- QuVa008067
227			QuVa008056- QuVa008061
228	QuVa Letter to FDA nominating Vasopressin for bulk drug substance	04-19-2017	QuVa007770- QuVa007772
229	Resume of Travis Leeah		QuVa007773- QuVa007775
230	Par exit interview with Ashley Short (Crist Depo. Ex. 37)	05-05-2017	Par-0002050-Par-0002051
231	Kennedy email to Ashley Short	02-02-2017	Par-0039147-Par-0039148
232	Moon email re Ashley Short interview schedule	04-07-2017	QuVa005135- QuVa005136
233	David Short email chain regarding Ashley Short	03-26-2017	QuVa005144- QuVa005146
234	Ashley Short resume		QuVa005230- QuVa005231
235	Par exit interview with Chinnasamy Subramaniam (Crist Depo. Ex. 36)	06-27-2017	Par-0002048-Par-0002049
236	Careers@QuVa email to D. Short re Chinnasamy Subramaniam resume	01-07-2016	QuVa005182
237	Chinnasamy Subramaniam resume		QuVa005315- QuVa005317
238	Timeline titled "No Contact with Par Employees Was Initiated by QuVa."		
239	QuVa letter to Subramaniam rescinding employment offer	02-25-2016	QuVa006254

240	QuVa employment offer to Chinnasamy Subramaniam	01-28-2016	QuVa006255- QuVa006257
241	Par exit interview with Hartley (Crist Depo. Ex. 33)	03-11-2016	Par-0002056-Par-0002057
242	David Michael (Mike) Hartley resume		QuVa005248- QuVa005251
243	Hartley employment application with QuVa	02-01-2016	QuVa005318- QuVa005319
244	QuVa employment offer to Hartley	02-03-2016	QuVa005660- QuVa005662
245	Par exit interview with Travis McGrady (Crist Depo. Ex. 31)	02-12-2016	Par-0002052-Par-0002053
246	McGrady resignation letter to Par	02-01-2016	Par-0002810
247	McGrady 2015 Mid-Year Performance Appraisal	07-10-2015	Par-0003438-Par-0003440
248	McGrady resume		QuVa005240- QuVa005242
249	McGrady employment application with QuVa	01-20-2016	QuVa005320- QuVa005321
250	McGrady email to Rhoades	12-17-2015	QuVa006390
251	QuVa employment offer to McGrady	01-22-2016	QuVa007644- QuVa007646
252	Qualitest Pharmaceuticals exit interview questionnaire by Soliman	12-03-2015	Par-0038850-Par-0038853
253	Fillarini email to Soliman re Ashley Short	04-04-2017	QuVa005775
254	QuVa employment offer to Soliman	04-21-2016	QuVa005900- QuVa005902
255	Soliman resume		QuVa006753- QuVa006755
256	Par exit interview with Thompson (Crist Depo Ex. 35)	10-14-2016	Par-0002054- Par-0002055
257	Thompson resume		QuVa005244
258	Careers@QuVa email chain re Thompson resume	01-21-2016	QuVa006029
259	Thompson employment application with QuVa	10-26-2016	QuVa007588- QuVa007592
260	QuVa employment offer to Thompson	11-01-2016	QuVa007595- QuVa007597
261	Kohut resume		QuVa007679- QuVa007682
262	QuVa employment offer to Kohut	08-28-2015	QuVa007579- QuVa007581
263	Rutkowski resume		QuVa006386- QuVa006490

264	A history of the OOS problem, BioPharm International		Rutkowski HardDrive-1-0000001-003
265	Position Paper: Segregation of Production Activities for Human and Animal Health Products		Rutkowski HardDrive-1-0000004-008
266	Braun internal memorandum from Gall re B. The Solution	01-16-2014	Rutkowski HardDrive-1-0000009-012
267	Par letter of recommendation for Dajour Simpson	04-03-2017	Rutkowski HardDrive-1-0000013
268	Rutkowski letter to Rochester employees	12-31-2013	Rutkowski HardDrive-1-0000014
269			Rutkowski HardDrive-1-0000015-018
270			Rutkowski HardDrive-1-0000019-021
271		05-04-2016	Rutkowski HardDrive-1-0000022-023
272	Group Leader, roles and responsibilities		Rutkowski HardDrive-1-0000024
273	Rutkowski letter of recommendation for DeAnn Johnson		Rutkowski HardDrive-1-0000025
274	ISO 8 clean room areas cleaning sanitization		Rutkowski HardDrive-1-0000026-037
275			Rutkowski HardDrive-1-0000038-043
276			Rutkowski HardDrive-1-0000044-045
277	Rutkowski letter of recommendation for Dajour Simpson		Rutkowski HardDrive-1-0000046
278	Rutkowski letter to The Rock	03-30-2017	Rutkowski HardDrive-1-0000047
279	Rutkowski resignation letter	03-28-2017	Rutkowski HardDrive-1-0000048
280			Rutkowski HardDrive-1-0000049-051
281			Rutkowski HardDrive-1-0000052-054
282	Par Rochester Site Manifesto		Rutkowski HardDrive-1-0000055
283	Rutkowski letter to Gustafson re common stock		Rutkowski HardDrive-1-0000056

284			Rutkowski
			HardDrive-1-0000057-058
285	WG Henschen job description for Operations		Rutkowski
	Manager		HardDrive-1-0000059-060
286		09/13/2011	Rutkowski
			HardDrive-1-0000061-064
287			Rutkowski
			HardDrive-1-0000065-068
288			Rutkowski
			HardDrive-1-0000069-072
289			Rutkowski
			HardDrive-1-0000073-075
290			Rutkowski
			HardDrive-1-0000076-078
291			Rutkowski
			HardDrive-1-0000079
292			Rutkowski
			HardDrive-1-0000080
293			Rutkowski
			HardDrive-1-0000081-083
294			Rutkowski
		00/4=/2046	HardDrive-1-0000084-089
295		08/17/2016	Rutkowski
20.6			HardDrive-1-0000090-093
296			
297	FDA's Quality Metrics Report Program: Submission		QuVa007683-
	of Quality Metrics Data		QuVa007684
298	Transcript of Rutkowski deposition	10-27-2017	
299	Hinchen email chain with Rhoades	08-17-2015	QuVa006479-
			QuVa006480
300	David Short email chain with Hinchen, re: Hello	09-04-2015	QuVa006636-
			QuVa006637
301	Kohut email chain with Kaminsky, re : Employment Letter A Ashford	01-11-2016	QuVa006688
302	Chinnasamy email to careers at QuVa , re: Resume – Chinnasamy Subramaniam	01-06-2016	QuVa006689
303	Kaminsky email chain with David Short, re: candidate for Director of Analytical Lab R&D – Ahmed Soliman	03-09-2016	QuVa006751- QuVa006752

304	David Short Resume		QuVa007675- QuVa007678
305	Stephen J. Rhoades Resume		QuVa007776- QuVa007778
306	Technical Report No. 13 (Revised) Fundamentals of an Environmental Monitoring Program, PDA 2014	2014	QuVa007831- QuVa007869
307	Technical Report No. 22 (Revised 2011) Process Simulation for Aseptically Filled Products, PDA 2011	2011	QuVa007781- QuVa007830
308	Rutkowski Proprietary Information and Nondisclosure Agreement with Endo		QuVa007779- QuVa007780
309	USP 1790, Visual Inspection of Injections, First Supplement to USP 40-NF 35, pp. 8099-8119	12-01-2017	QuVa008214- QuVa008234
310	Technical Report No. 36, Current Practices in the Validation of Aseptic Processing – 2001, PDA Journal of Pharmaceutical Science and Technology, Vol. 56, May-June 2002	05-01-2002	QuVa008176- QuVa008213
311	Technical Report No. 20, Report on Survey of Current Industry Gowning Practices, PDA Journal of Pharmaceutical Science and Technology, Sup. Vol. 44, No. S2 (1990)	01-01-1990	QuVa008170- QuVa008175
312	ISO 13408-1 2008E, Aseptic Processing of Health Care Products, Part 1: General Requirements	06-15-2008	QuVa008068- QuVa008121
313	USP 38 (797) Pharmaceutical Compounding – Sterile Preparations	12-1-2015	QuVa008235- QuVa008279
314	Schwartz, "UPLC <sup>TM</sup> : An Introduction and Review", Journal of Liquid Chromatography and Related Technologies, 28:1252-1263 (2005)	2005	QuVa008159- QuVa008169
315	Chart comparing QuVa 503B compounding with Par traditional sterile manufacturing		
316	Nema et al., "Excipients and Their Use in Injectable Products", PDA J. Pharm. Sci. and Tech., 51:166- 171 (1997)	1997	QuVa008128- QuVa008135
317	Pinal CV		QuVa008136- QuVa008158
318	List of materials considered by Pinal		
319		07-31-2015	QuVa000838- QuVa000839
320		09-24-2017	QuVa002110- QuVa002111; QuVa002114- QuVa002133-
321	Hyodo, Chapter 6A, Vasopressin (2016)		QuVa008482- QuVa008486

Streitwieser, Heathcock, "Introduction to Organic Chemistry" 2nd Ed., p. 54		
Transcript of Peter Jenkins deposition as individual	11-09-2017	
Transcript of Peter Jenkins deposition as 30(b)(6) witness	11-09-2017	
Par's Supplemental Responses to Defendants' First Set of Interrogatories (Crest Depo. Ex. 3)	10-26-2017	
Par exit interview with David Short (Crist Depo. Ex. 27)	10-23-2015	Par-0002058-Par-0002059
Par exit interview with Steve Rhoades (Crist Depo. Ex. 29)	10-16-2015	Par-0002060-Par-0002061
Rutkowski email chain with Campaneli (Crist Depo Ex. 39)	04-10-2017	Par-0038733-Par-0038735
Endo and Soliman Mutual Agreement to Arbitrate Claims	02-11-2016	Par-0001547-Par-0001549
Kaminsky email chain with Hinchen re David Short	10-12-2015	QuVa006510- QuVa006512
PIC's Recommendation on the Validation of Aseptic Processes PL 007-6	01-01-2011	QuVa008487- QuVa008506
White, "Aseptic Process Simulation", J. Validation Tech (Winter 2010) pp 39-42.	12-01-2010	QuVa008507- QuVa008510
"Media fill simulations", Focus on Pharma, Manufacturing Chemist, Quality Assurance	11-00-2014	QuVa008479- QuVa008481
Resume of Ludmila Yaheva		QuVa008511- QuVa008513
Resume of Chen Jianping		QuVa008514- QuVa008517
"Par - People Achieving Results," <www.parpharm.com></www.parpharm.com>		
Par Pharmaceutical Holdings, Inc.'s Form S-1, March 12, 2015	03-12-2015	
Endo Completes Acquisition of Par Pharmaceutical and Provides Financial Guidance, Endo International plc Press Release	09-28-2015	
"Overview," <www.endo.com></www.endo.com>		
"Careers" <www.quvapharma.com></www.quvapharma.com>		
"Vasostrict Medical Review(s)," Center for Drug Evaluation and Research, April 4, 2014	04-04-2014	
Vasostrict Label, Par Pharmaceutical Companies, Inc., April 17, 2014, accessed via <a href="https://www.accessdata.fda.gov">www.accessdata.fda.gov</a>	04-17-2014	
"Some Selected History of Oxytocin and Vasopressin," The National Institute of Mental Health		
	Chemistry" 2nd Ed., p. 54  Transcript of Peter Jenkins deposition as individual  Transcript of Peter Jenkins deposition as 30(b)(6) witness  Par's Supplemental Responses to Defendants' First Set of Interrogatories (Crest Depo. Ex. 3)  Par exit interview with David Short (Crist Depo. Ex. 27)  Par exit interview with Steve Rhoades (Crist Depo. Ex. 29)  Rutkowski email chain with Campaneli (Crist Depo Ex. 39)  Endo and Soliman Mutual Agreement to Arbitrate Claims  Kaminsky email chain with Hinchen re David Short  PIC's Recommendation on the Validation of Aseptic Processes PL 007-6  White, "Aseptic Process Simulation", J. Validation Tech (Winter 2010) pp 39-42.  "Media fill simulations", Focus on Pharma, Manufacturing Chemist, Quality Assurance  Resume of Ludmila Yaheva  Resume of Chen Jianping  "Par - People Achieving Results," <www.parpharm.com>  Par Pharmaceutical Holdings, Inc.'s Form S-1, March 12, 2015  Endo Completes Acquisition of Par Pharmaceutical and Provides Financial Guidance, Endo International plc Press Release  "Overview," <www.endo.com>  "Careers" <www.quvapharma.com>  "Careers" <www.quvapharma.com>  "Careers" <www.quvapharma.com>  "Careers" <www.quvapharma.com>  "Careers" <www.quvapharma.com>  "Vasostrict Medical Review(s)," Center for Drug Evaluation and Research, April 4, 2014  Vasostrict Label, Par Pharmaceutical Companies, Inc., April 17, 2014, accessed via &lt; www.accessdata.fda.gov&gt;  "Some Selected History of Oxytocin and Vasopressin," The National Institute of Mental</www.quvapharma.com></www.quvapharma.com></www.quvapharma.com></www.quvapharma.com></www.quvapharma.com></www.endo.com></www.parpharm.com>	Chemistry" 2nd Ed., p. 54  Transcript of Peter Jenkins deposition as individual Transcript of Peter Jenkins deposition as 30(b)(6) witness  Par's Supplemental Responses to Defendants' First Set of Interrogatories (Crest Depo. Ex. 3)  Par exit interview with David Short (Crist Depo. Ex. 27) Par exit interview with Steve Rhoades (Crist Depo. Ex. 29)  Rutkowski email chain with Campaneli (Crist Depo Ex. 29)  Rutkowski email chain with Campaneli (Crist Depo Ex. 39)  Endo and Soliman Mutual Agreement to Arbitrate Claims Kaminsky email chain with Hinchen re David Short  PIC's Recommendation on the Validation of Aseptic Processes PL 007-6  White, "Aseptic Process Simulation", J. Validation Tech (Winter 2010) pp 39-42.  "Media fill simulations", Focus on Pharma, Manufacturing Chemist, Quality Assurance  Resume of Ludmila Yaheva  Resume of Chen Jianping  "Par - People Achieving Results," <www.parpharm.com>  Par Pharmaceutical Holdings, Inc.'s Form S-1, March 12, 2015  Endo Completes Acquisition of Par Pharmaceutical and Provides Financial Guidance, Endo International plc Press Release  "Overview," <www.endo.com>  "Careers" <www.quvapharma.com>  "Vasostrict Medical Review(s)," Center for Drug Evaluation and Research, April 4, 2014  Vasostrict Label, Par Pharmaceutical Companies, Inc., April 17, 2014, accessed via <www.accessdata.fda.gov>  "Some Selected History of Oxytocin and Vasopressin," The National Institute of Mental</www.accessdata.fda.gov></www.quvapharma.com></www.endo.com></www.parpharm.com>

344	Warner-Lambert & King In \$125M Deal," The Pharma Letter, April 3, 1998	04-03-1998	
345	King Pharmaceuticals, Inc.'s Form 8-K, July 19, 2007	07-19-2007	
346	"Vasopressin Injection Drug Shortage Notice," <www.drugs.com></www.drugs.com>		
347	Declaration of Peter Jenkins, September 5, 2017	09-05-2017	
348	"What are unapproved drugs and why are they on the market?" <www.fda.gov></www.fda.gov>		
349	Defendants' Opposition to Par's Motion for Expedited Discovery	09-07-2017	
350	"Guidance for FDA Staff and Industry: Marketed Unapproved Drugs — Compliance Policy Guide," Center for Drug Evaluation and Research at the FDA, September 19, 2011	09-19-2011	
351	"Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act," Food and Drug Administration, Updated July 1, 2017	07-01-2-17	
352	"Compounding and the FDA: Questions and Answers," <www.fda.gov></www.fda.gov>		
353	Vasostrict Label, Par Pharmaceutical Companies, Inc., December 21, 2016, accessed via <a href="https://www.accessdata.fda.gov">www.accessdata.fda.gov</a>	12-21-2016	
354	Roman L. Weil, Daniel G. Lentz, and Elizabeth A. Evans, eds., Litigation Services Handbook: The Role of the Financial Expert, Sixth edition, John Wiley and Sons, 2017, Chapter 4: "Damages Theories and Causation Issues"	2017	
355	Par Sterile Products website, Par Product Summary: Vasostrict," <www.parsterileproducts.com></www.parsterileproducts.com>		
356	Update: FDA revises final guidances on interim policy for certain bulk drug substances used in compounding," <www.fda.gov></www.fda.gov>		
357	4Q Wrap-Up: Modest Sales Beat, but Lowering Ests on Pessimistic '17 Guide," Leerink, February 28, 2017	02-28-2017	Par-0040106-Par-0040116
358	Truven Health Analytics, "AWP Policy," Revised October 1, 2014	10-01-2014	
359	Truven Health Analytics website, "RED BOOK," <a href="https://www.truvenhealth.com">www.truvenhealth.com</a>		
360	Michael Hiltzik, "The little-known FDA program that's driving drug prices higher," LA Times, September 23, 2015	09-23-2015	
361	"Some Drug Price Hikes Due to FDA Safety Program," News Max, October 7, 2015	10-07-2015	
362		11-08-2017	Par-0039612-Par-0039614

363			Par-0040199
364	"Lowering Ests, Persistent US Gx Headwinds, Lowering PT to \$12," Leerink Partners	01-24-2017	Par-0040117-Par-0040127
365	Endo International Plc's 10-K for fiscal year ended December 31, 2015	12-31-2015	
366	Endo International Plc's 10-K for fiscal year ended December 31, 2016	12-31-2016	
367	Endo International plc's 10-Q for quarterly period ended September 30, 2017	09-30-2017	
368	Par Sterile Products – Products Database		Par-0040158-Par-0040161
369	Par Pharmaceutical – Product Catalog, <www.parpharm.com></www.parpharm.com>		
370	"Vasostrict Summary Review," Center for Drug Evaluation and Research, Application Number 204485Orig1s000, March 20, 2014	03-20-2014	
371	"Outsourcing Facilities," <www.fda.gov></www.fda.gov>		
372	Jennifer Gudeman, Michael Jozwiakowski, John Chollet, and Michael Randell, "Potential risks of pharmacy compounding," Drug RD, Vol 13, March 23, 2013	03-23-2013	
373	American Regent, Inc. Initiates Voluntary Recall of Seventeen Lots of Vasopressin Injection, USP, Multiple Dose Vials due to Sub-Potency," PR Newswire, August 3, 2011	08-03-2011	
374	"PHAST Prescription," Symphony Health		
375	Hoefle, "The Early History of Parke-Davis and Company", Bulletin for the History of Chemistry 25, No. 1 (2000)	2000	
376	Vasostrict Supplemental New Drug Application Approval Letter, Par Pharmaceutical Companies, Inc.	12-16-2016	
377			Par-0039661-Par-0039662
378	American Regent website, Our Company, <www.americanregent.com></www.americanregent.com>		
379	Center for Drug Evaluation and Research Approval Package for Application Number: 204485Orig1s004, Vasostrict	121-16- 2016	
380	"How did the Federal Food, Drug, and Cosmetic Act come about?" <www.fda.gov></www.fda.gov>		
381	Symphony Health Integrated Pharmaceutical Audit Suite data		
382	Truven Health Analytics Red Book Online Product Details: Pitressin, Vasostrict		
383	List of materials Considered by Patterson		
384	CV of Brian T. Wolfinger		
385	List of Materials Considered by Brian T. Wolfinger		

386	Chart titled: Thumb Drive Identification Chart		
387	Photos taken by Brian T. Wolfinger of the Lenovo drive		
388	Image log for the image provided of Ashley Short's hard drive		
389	Image log for the image provided of Chinnasamay Subramaniam's hard drive		
390	Image log for the image provided of Mike Rutkowski's hard drive		
391	Screenshot provided from the forensic analysis conducted by Brian T. Wolfinger		
392	Screenshot provided from the forensic analysis conducted by Brian T. Wolfinger, containing the title "Post Departure Disk Defragmentation: Screenshot of Software Analysis."		
393	Lenovo Website, X1 Carbon 2 <sup>nd</sup> Gen (Type 20A7, 20A8) Laptop (ThinkPad)		
394	Lenovo Magazine Website, How and When to Defragment Your Hard Drive in Windows 10		
395	Document titled "Defrag & Summary Data," prepared by Wolfinger Forensics		
396	Screenshot provided from the forensic analysis conducted by Brian T. Wolfinger, containing the heading: Operating System Install Dates for Rutkowski and Subramaniam.		
397	Custody Documents from Par		Par-0040242-Par-0040253
398	Screenshot provided from the forensic analysis conducted by Brian T. Wolfinger		
399	Text message screenshots		OMM-SC-0000047-53
400	November 15, 2017 correspondence from Jenny Liu to DriveSavers		OMM-SC-0000001
401	Par Supplemental Responses to Interrogatories Nos. 1, 5, 8 and 9	10-30-2017	
402	Bi et al., "HPLC Method for Quantification of Arginine Containing Vasopressin", J. Liq. Chrom. & Rel. Technol. 22(4):551-560 (1999)	1999	
403	Hermann et al., "Urinary excretion of angiotensin I, II, arginine vasopressin and oxytocin in patients with anaphylactoid reactions", Clinical and Experimental Allergy, 22:845-853 (1992)	1992	
404	Tsukakzaki et al, "Development of a High- Sensitivity Quantitation Method for Arginine Vasopressin by High-Performance Liquid Chromatography Tandem Mass Spectrometry, and Comparison with Quantitative Values by Radioimmunoassay", Analytical Sciences, 32:153- 159 (February 2016).	02-2016	
405	Zhang et al. "Development and validation of a highly sensitive LC-MS/MS assay for the quantification of	2014	

	arginine vasopressin in human plasma and urine: Application in preterm neonates and child", J. Pharm.	
10.5	& Biomedical Analysis, 99:67-73 (2014)	
406	CV of Mohan Rao	
407	List of Materials Considered by Mohan Rao	
408	Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug and Cosmetic Act, Guidance for Industry	January 2017
409	Transcript of September 29, 2017 hearing on expedited discovery	09-30-2017
410	Declaration of Ahmed Soliman	12-05-2017
411	Declaration of Angela Palomarez	12-07-2017
412	Declaration of Ashley Short	12-06-2017
413	Declaration of Chinnasamy Subramaniam	12-05-2017
414	Declaration of David Michael Hartley	12-07-2017
415	Declaration of David Short	12-05-2017
416	Declaration of Donna Kohut	12-04-2017
417	Declaration of Guy Thompson	12-06-2017
418	Declaration of John B.White	12-04-2017
419	Declaration of Mike Rutkowski	12-06-2017
420	Declaration of Stephen Rhoades	11-30-2017
421	Declaration of Stuart Hinchen	12-06-2017
422	Declaration of Travis Leeah	12-06-2017
423	Declaration of Travis McGrady	12-01-2017
424	Declaration of Harold Patterson	
425	Declaration of Dr. Rodolfo Pinal	
426	Declaration of Brian T. Wolfinger	12-07-2017
427	Declaration of Dr. Mohan P. Rao	